K000308

MAY 1 9 2000

SECTION 10
510(K) SUMMARY

FOI RELEASABLE

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific Corporation chooses to submit a summary of information respecting safety and effectiveness.

- DATE: January 31, 2000
- COMMON/USUAL NAMES: Biliary Stent
- TRADE/PROPRIETARY NAME: Microvasive Biliary Wallstent
- CLASSIFICATION NAME & DEVICE CLASSIFICATION: Class II

Name	Number	21 CFR Ref.
Biliary Catheter and Accessories	78 FGE.	876.5010

- DEVICE PANEL/BRANCH: Gastroenterology-Urology (GU)
  Gastro-Renal (GRDB)
- OWNER/OPERATOR: Boston Scientific Corporation
  One Boston Scientific Place
  Natick, MA 01760
- CONTACT PERSON: Lisa M. Quaglia, Regulatory Affairs Manager

DESCRIPTION OF DEVICE

The Microvasive *Modified Biliary* Wallstent® is comprised of two components: the implantable metallic stent and the Unistep Plus delivery system. The stent is composed of biomedical superalloy monofilament wire, braided in a tubular mesh configuration and covered with a silicone polymer. Approximately five (5) millimeters of bare metal braid is exposed at each end of the covered stent. This design configuration results in a stent that is flexible, compliant and self-expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during delivery. Radiopaque marker bands situated on the interior and exterior tubes aid in imaging during deployment. The stent wires may have a

radiopaque core to improve radiopacity. The interior tube of the coaxial system contains a central lumen which will accommodate a 0.035"/0,89 mm guidewire.

INDICATIONS FOR USE

The *Modified Biliary Wallstent®* is indicated for use in the treatment of Biliary strictures produced by malignant neoplasms.

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

Boston Scientific Corporation believes that the Modified Biliary Wallstent® is substantially equivalent to the currently-marketed Biliary Wallstent® and the currently marketed Tracheobronchial Wallstent®. The major components of the Modified Biliary Wallstent® are the stent and the delivery system. A thorough comparison of the descriptive characteristics between the Modified Biliary Wallstent® and the predicate devices show equivalence.

PERFORMANCE CHARACTERISTICS

Laboratory testing regarding characteristics was performed on Modified Biliary Wallstent® to verify its safety and performance. A biocompatibility assessment was performed on the patient- and fluid-contact materials of the Modified Biliary Wallstent® with satisfactory results.

CONCLUSION

Boston Scientific Corporation believes that Modified Biliary Wallstent® is substantially equivalent to the currently-marketed Modified Biliary Wallstent® and the currently marketed Tracheobronchial Wallstent®. A comparison of the descriptive characteristics of these products demonstrate the Modified Biliary Wallstent® is equivalent in its indications for use, while being very similar in design and materials. In addition, Boston Scientific Corporation has presented laboratory testing and biocompatibility information. The information presented provides assurance that the Modified Biliary Wallstent® will meet the minimum requirements that are considered acceptable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 9 2000

Ms. Lisa M. Quaglia
Regulatory Affairs Manager
Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537

Re: K000308
Modified Biliary Wallstent® (Silicone Covered Stent)
Regulatory Class: II
21 CFR 876.5010
Product Code: 78 FGE
Dated: May 5, 2000
Received: May 8, 2000

Dear Ms. Quaglia:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Robert R Nathing /

David W. Feigal, Jr., M.D., M.P.H.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000308

Device Name: Modified Biliary Wallstent®

FDA's Statement of the Indications For Use for device:

The *Modified Biliary Wallstent*® is indicated for use in the treatment of biliary strictures produced by malignant neoplasms.

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

David A. Lyman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000308